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THE EFFECT OF CHELATION THERAPY UPON THE  
PERCEPTUAL QUALITY OF LIFE AND THE  
PERCEPTION OF PAIN IN CLIENTS  
RECEIVING INFUSIONS

by

FRANCINE GLENN

A Thesis  
Submitted in Partial Fulfillment of the Requirements  
for the Degree of Master of Science in Nursing  
in the Division of Nursing  
Mississippi University for Women

COLUMBUS, MISSISSIPPI

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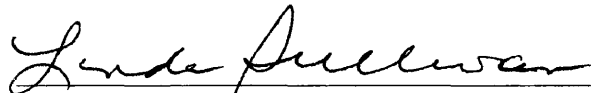
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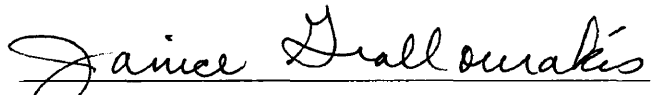
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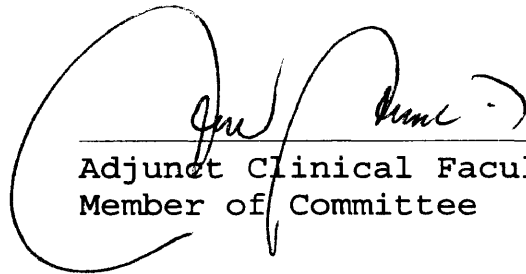
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## Abstract

The use of ethylenediaminetetraacetic acid (EDTA) for chelation in patients with diseases of the circulatory system has been a controversial issue for several decades. However, there was a lack of studies substantiating the perceived benefits of patients receiving chelation therapy. The purpose of this study was to examine the effect on pain and perceived benefits related to the quality of life for patients receiving chelation infusions. The theoretical framework that guided this study was the Health Promotion Model developed by Nola J. Pender. The research questions were what are the effects of chelation therapy on the perceptual quality of life in patients receiving infusions and what are the effects of chelation therapy on the pain of patients receiving infusions? The perceptual quality of life and pain variables were measured using the EORTC QLQ-C30 and the Medical Outcomes Study questionnaires. The Pearson product-moment correlation (Pearson  $r$ ) and descriptive statistics were used to analyze the data. Content analysis was utilized for open-ended questions in the survey. The

sample consisted of 24 clients currently receiving chelation therapy. The study found four areas related to the quality of life significant: an increase in cognitive functioning and a decrease in levels of fatigue, insomnia, and financial difficulty. Overall, pain was perceived as low in the majority of clients in this study. Findings from this study indicated that clients did notice an improvement of their overall health status and experienced little or no pain. Recommendations for future research were included in this study and conduction of more studies utilizing different methodology so as to validate the efficacy of alternative health treatments.

## Dedication

This research endeavor is dedicated to my friend, Melanie Thompson, and my family, Ricky, Renee, Crystal, and Jarvis Glenn. Thank you for your constant support and inspiration during the past 12 months. Thanks for helping me to see the light at the end of the tunnel.

## Acknowledgments

I would like to express my appreciation to Dr. Linda Sullivan, who served as my advisor and the chairperson of my research committee. I would also like to thank Dr. Jacob Skiwiski and Janice Giallourakis, members of my research committee. Thank you for your patience, kindness, and suggestions.

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## Chapter I

### The Research Problem

The purpose of this chapter will be to provide an establishment of the problem along with the theoretical framework supported by current literature. The chapter will also include definitions of the variables and assumptions that are relevant to the current researcher.

Alternative health care intervention is an emerging concept within the health care system. Many health care professionals are challenged by the controversial issues surrounding alternative intervention versus traditional medical practices. There are a multitude of alternative interventions that include, but are not limited to, acupuncture, homeopathy, herbal therapies, chiropractic, massage, exercise/movement, high-dose megavitamins, spiritual healing, lifestyle diet, relaxation, imagery, energy healing, folk remedies, biofeedback, hypnosis, psychotherapy, chelation, and art-music therapy.

### Purpose of the Study

The purpose of this study was to investigate the effect of chelation therapy upon the perception of the quality of life and pain of clients receiving chelation infusions.

### Establishment of the Problem

Alternative health care interventions is a topic of controversy in today's medical arena. Just as there is diversity of health care needs, there is a diversity of health care practices available to address these needs. Jonas (1997) does not see alternative practices as a replacement for conventional medicine but as an adjunct when conventional medicine requires supplementation and support. Jonas (1997) concluded that alternative therapy is here to stay, influenced by an increasing demand and search for lower health care costs.

Jonas (1997) defines alternative health care interventions as those practices used for the prevention and treatment of disease that are not normally taught in medical schools and not generally available inside hospitals. It includes practices requiring highly

specialized and competent practitioners and many over-the-counter products and self-care techniques.

Alternative therapies are no longer considered a fad. Today, many clients seek those nontraditional treatments (Keegan, 1998). Keegan attributes an increase in the use of alternative therapies to a holistic approach and the wish for noninvasive techniques. Discussion of alternative interventions with clients will result in a more informed decision by clients concerning the choice of alternative health care interventions versus traditional medicine.

Health care providers are divided on the significance of the trend of increased visits to alternative practitioners. The use of alternative interventions is increasing as consumers become more knowledgeable regarding alternative medicine. A recent survey of 1,035 respondents showed that 40% used some type of alternative therapy in the past year (Astin, 1998). The increase in popularity of alternative interventions has led several insurance companies to cover certain alternative treatments. The significance to nursing is the need to be informed about new and upcoming medical treatments. Studies validating the benefits to clients receiving chelation therapy will help primary care providers

consider alternative health care interventions as viable options to the treatment of chronic and degenerative diseases that affect perceptual quality of life and perception of pain.

In 1997, a national study surveyed 1,500 American adults. Forty-two percent of the population related use of various forms of alternative health care. The increased usage of alternative health care has been attributed to successful public relations and an increase in education concerning alternative care. The majority of the population identified with excellent health and satisfaction with the provider of alternative health care (National Council Against Health Fraud, 1998).

Jonas (1997) supports education in regard to the type of alternative health care practices available. The client should be guided by the family health care provider. Guidance makes it necessary for the health care provider to be aware of the side effects and interactions with standard health care practices. Jonas (1997) concluded that alternative therapy is here to stay.

Arteriosclerosis is one of the most debilitating diseases of the world today and the leading cause of disability and death (Walker, 1990). More than 10 million

people in the United States suffer from cardiovascular disease (CVD), and more than 2 million have a myocardial infarction (MI) or coronary artery bypass surgery each year (Schaer, Stein, & McBride, 1998). When blood vessels become blocked by plaque, bloodflow to vital organs is reduced. This blockage can cause symptoms such as chest pain, leg pain with walking, shortness of breath, painful or discolored feet, and transient loss of memory or vision. These symptoms may contribute to lifestyle limitations as well as experiences of pain with daily activities of living, thus affecting the perception of the quality of life and/or the perception of pain.

Narrowing and occlusion of vessels may occur not only in large vessels but also in small vessels. Vascular disease leads to reduced blood flow to many vital organs and tissues. This reduction in blood flow can result in the development of stroke, renal disease, mental status changes, and other physical changes. These complications can have a direct affect or effect on the quality of life by restriction of activities and pain. Peripheral vascular disease can lead to intermittent claudication which can cause pain with walking, exercise, or at rest. These conditions can produce a decrease in the perceptual



quality of life and health. "Persons who have chronic health conditions or disabilities are especially vulnerable to pain, depression, anxiety, sleeplessness, and lack of vitality" (U. S. Department of Health and Human Services, 1998).

Chelation therapy is an alternative intervention that has been used with clients diagnosed with problems of the circulatory system, such as arteriosclerosis of peripheral vessels, coronary heart disease, and other vascular diseases. Because of the triumph over infectious diseases and diseases of childhood, many people have begun to survive into old age, which has brought on a rapid rise and dominance of cardiovascular disease as the overwhelming cause of illness and death in the United States adult population and in other industrial nations (Mallory & Bahinski, 1999). This disease threatens to place an extraordinary burden on worldwide health care resources and practices of medicine by the year 2000. Cardiovascular disease is also seen as a cause of morbidity and the leading cause of death in virtually all countries of the world. Alternative health care interventions may have an effect on the perceptual quality

of life or the perception of pain in clients receiving chelation intervention.

These degenerative diseases have been treated by traditional medical surgical treatments and medical treatment. In the past, traditional medicine did not recognize any benefits of alternative interventions in the treatment of vascular disease or its affect on an individual's perception of quality of life and pain (McDonagh, 1987). However, current literature recognizes that there are some benefits to clients who utilize alternative treatments.

The American Heart Association has estimated the cost of cardiovascular disorders in 1998 at \$259 billion. Surgical treatment of vascular disease is very costly. Today, the average bypass surgery costs over \$35,000 per procedure (Edelson, 1995). The cost of diagnostic tests is not included in this cost. Chelation therapy costs approximately \$90 to \$100 per treatment. The average client receives 30 to 40 treatments over the course of approximately 3 years, resulting in a total cost of approximately \$3,000 over a period of 3 to 4 years. This presents a savings of approximately \$32,000. The cost comparison of surgery versus chelation therapy supports a

alternative interventions with clients with chronic diseases who may benefit from these interventions.

Also, government and private insurances continuously search for ways to reduce the cost of health care practice and to efficiently utilize health care dollars. This study will support the examination of alternative health interventions as a reduction in cost for managing chronic diseases. As there continues to be an increase in the use of alternative health care interventions, there will develop a need for more medical insurance companies to consider coverage of payments for alternative health care interventions. This coverage will lead to more research involving the benefits of alternative health practices and interventions.

#### Theoretical Framework

The Health Care Promotion Model (Marriner-Tomey & Alligood, 1998) will provide the theoretical framework for this study. Pender identifies cognitive-perceptual factors that are modified by situational, personal, and interpersonal characteristics to result in the participation in health-promoting behaviors. Pender identifies the following seven primary motivational

mechanisms for the actions related to health promotion:

(a) importance of health, (b) perceived control of health, (c) perceived self-efficacy, (d) definition of health, (e) perceived health status, (e) perceived benefits of behaviors, and (f) perceived barriers to health-promoting behaviors (Marriner-Tomey & Alligood, 1998).

Using Pender's model, clients receiving chelation therapy as an alternative intervention value their health status which influences their decision to select alternatives in health care. Being in a well state is a top priority for these clients, and they perceive themselves as being in control of their wellness state. This perception is manifested by the decision to engage in an alternative intervention that gives more control to achieve their health status goal. The individual's self-efficacy and perceived health status are based primarily on the subjective measurements of the client's decision to engage in an alternative intervention. The perceived health benefits investigated in this study were determined by the subjective expressions of these clients based on the correlation between chelation infusions and their perceptual benefits from selecting and engaging in this alternative to mainstream medicine.

For the purpose of this study, the individual was the client who received chelation therapy. The individual is the center of the model. The individual's choice and selection of chelation therapy are influenced by several of the primary motivational mechanisms identified in the Health Promotion Model. This model places responsibility on the individual to take an active role in the selection of health-promoting behaviors. The individual's definition and perception of health have more importance than any other factors that influence health.

The practitioner uses Pender's theory to promote the individual's health. The attainment of personal health is essential for health care providers and consumers. This theory is a primary tool in nursing research.

#### Statement of the Problem

Alternative methods of providing medical treatment for a variety of health care problems is becoming more popular. Traditional medicine and insurance companies continue to not recognize the benefits of alternative methods of health care; therefore, more research is needed. The use of repeated chelation infusions has been promoted for the treatment of a wide range of disorders.

These disorders include arteriosclerosis, intermittent claudication, cerebrovascular disease, and other diseases of the circulatory system. There have been reports of clinical benefits of clients who have received infusions. However, there is a lack of research substantiating the effects and benefits of chelation therapy. Thus, the problem investigated in this study was the effects of chelation therapy upon the perceptual quality of life and the perception of pain in clients receiving chelation infusions. The purpose of this study was to determine the effect upon the perception of the quality of life and the perception of pain in clients receiving chelation infusions.

#### Research Questions

1. What is the effect of chelation therapy upon perceptual quality of life in clients receiving infusions?
2. What is the effect of chelation therapy upon the pain perception of clients receiving infusions?

#### Definition of Terms

For the purpose of this study, the following terms were defined:

Chelation therapy: Theoretical:

. . . the incorporation of a metal into a heterocyclic ring structure of the chelating agent, the result is a closed ring; when the metal joins the molecular structure of the chelating agent, the result is a closed ring. The metal is now a part of the new structure and is captive of the chelating agent (McDonagh, 1987, p. 83)

Operational: the administration of ethylenediaminetetraacetic acid (EDTA) through an intravenous access which rids the body of toxic heavy metals.

Perception of pain: Theoretical: ". . . an unpleasant sensory and emotional experience that is normally associated with injury to body tissues" (Grolier Electronic Encyclopedia, 1993, p. 254). Operational: an unpleasant sensory and emotional experience as a result of occlusive arterial disease determined by subjective report from clients receiving chelation therapy as operationalized by the Medical Outcomes Study (MOS).

Effect: Theoretical: ". . . the result of something that has been done or has happened" (Webster's Dictionary, 1994, p. 56). Operational: the result of chelation therapy on perception of quality of life and perception of pain as

determined by subjective measurements of clients receiving chelation therapy.

Client: Theoretical: ". . . an individual awaiting or under medical treatment" (Webster's Dictionary, 1994, p. 118). Operational: an individual undergoing chelation therapy as a form of alternative treatment.

Perceptual quality of life: Theoretical: the enjoyment of life that an individual experiences based on activities of daily living and the overall perception of health and the rise from deterioration (Grolier Encyclopedia, 1993). Operational: an individual's perception of the effect of chelation therapy upon their health status and their overall satisfaction and enjoyment of life as measured by the score on the European Organization for Treatment and Research of Cancer Quality of Life Questionnaire (EORTC QLQ-C30).

### Assumptions

For the purposes of this study, the following assumptions were made:

1. Clients used chelation therapy by infusion as an alternative treatment to traditional medicine.



2. Individuals with chronic disease perceived an optimal level of functioning as a realistically obtainable state or goal.

3. Individuals were motivated to engage in health promotion behaviors, perceived benefits, and treatments.

4. Subjective benefits related to pain and quality of life were measured with clients receiving chelation therapy.

## Chapter II

### Review of the Literature

The benefits of chelation infusions have been a controversial issue for several decades. There have been several studies that have investigated objective and subjective benefits of chelation infusions. This chapter will provide a critical evaluation of the review of literature and the variables under investigation.

Van Rij, Solomon, Packer, and Hopkins (1994) investigated the benefits of chelation therapy in patients with intermittent claudication. In their review of the literature, Van Rij et al. (1994) cited that much of the literature lacked the supportive evidence of experiments and appropriately designed clinical trials. The authors also cited many claims for the benefits of chelation therapy that were based on uncontrolled studies.

Van Rij et al. (1994) conducted a single-center, double-blind, randomized controlled trial in a group of patients to identify significant benefits of chelation therapy among patients with intermittent claudication.

These benefits were measured by obtaining subjective and objective data including (a) segmental pressure and pulse volume plethysmography and femoral and posterior tibial artery pulsatility indices, (b) exercise on treadmill, (c) level of cardiac function efficiency, and (d) behavior and attitudes related to lifestyles.

A sample of patients was recruited from the Dunedin Hospital Peripheral Vascular Disease Clinic. Criteria for inclusion were patients with atherosclerotic disease confirmed by arteriography, over the age of 45 years, and with no debilitating disease, diabetes, or significant renal disease. The final sample consisted of 32 patients who met the criteria, agreed to participate, and completed the treatment. Sample size required was calculated from an algorithm that combined retest reliability of outcome measures, Type I error rate, and power to detect a minimum difference in effect size between treatment ( $n = 15$ ) and control group ( $n = 17$ ). Subjects were randomized in blocks of 10 with assigned infusions prepared by the hospital pharmacists. Each patient received 20 infusions, twice per week over 10 weeks. The infusions were indistinguishable by label, color, or container.

Van Rij et al. (1994) found significant improvement in the walking distance of both groups at the end of the infusion program. However, the measurement of subjective walking distances as well as post-exercise ABI were not significantly different during treatment or follow-up. No significant differences in skinfold flow, transcutaneous oxygen, or pulse volume recordings after treatment emerged. Resting ankle and brachial indices of both the better and worse legs showed improvement of 0.1 in two patients in each group ( $p < .05$ ). There were no other changes in parameters of peripheral vascular function at 3 months after the treatment.

Changes in lifestyle parameters at the end of the period showed no difference between the two groups. The level of usual activity and low intensity and mild to moderate activity exercise all improved with the chelation group. Van Rij et al. found no benefits on assessed level of fatigue, physical well-being, mood, general quality of life, or on the specific effect of arterial disease on quality of life, work, home management, and social or private leisure activities.

The researchers concluded that chelation therapy provided no immediate benefit on peripheral vascular

hemodynamics, functional measures of activity, lifestyle, quality of life, or perceptions of health related to peripheral vascular disease when compared with a control group. Van Rij et al. concluded that the significance of improvement established with the assessments in the late findings would require further study.

This study was chosen for review because of similarities to the current researcher's endeavors. Van Rij et al. helped identify key methods of controlling variables. Also, the study design assisted the current researcher in maximizing variance control within the researcher's current study.

In another study, Olszewer, Sabbag, and Carter (1990) investigated the benefits of sodium magnesium (NaMg)-ethylenediaminetetraacetic acid (EDTA) in peripheral vascular disease. In their review of the literature, Olszewer et al. (1990) found that there were no double-blind clinical trials evaluating the effects of NaMgEDTA in the treatment of peripheral vascular disease. Therefore, the researchers employed a double-blind clinical trial with evaluation of the findings based on (a) the walking test, (b) the master test, and (c) the bicycle stress test.

A sample of 10 male patients with a mean age of 47 years with peripheral vascular disease was enrolled in the study. They all had intermittent claudication and 8 of the 10 had smoked and quit 6 months prior to the start of the study. The 10 patients were randomly and equally divided into two groups. Both groups received the nutritional additives to the intravenous solution. EDTA and distilled water were divided and supplied in unidentifiable bottles for infusion.

Data were obtained on 10 patients after 10 chelation treatments and 10 placebo infusions. At the end of the first 10 sessions, Olszewer et al. (1990) decided to break the code and continue the study on a single-blind basis. This decision was based on the significant improvement seen in one group later determined to be receiving EDTA. There was no control group for the next 10 sessions, and all subjects (N = 10) received the EDTA. Data were again collected at the end of the 20 sessions.

These data were analyzed with the repeated means method. Olszewer et al. (1990) found significant improvement in the three areas of clinical evaluation. At the end of the first 10 sessions, the walking distance doubled in the group receiving EDTA. After the 20<sup>th</sup>

infusion, the EDTA group walked nearly three times the distance when compared to the distance before the treatment ( $p = .06$  for the walking and  $p = .07$  for the master step). There were time effects and significant differences between baseline treatments and 10 treatments ( $p = .025$ ). The EDTA group doubled the distance walked before therapy. The researchers concluded that chelation had a significant impact on the walking distance, the two-step exercise test, and the bicycle stress test.

This study was chosen for review because of similarities to the current researcher's endeavors. Olszewer et al. (1990) helped to identify the need for incorporation of the variable of time into data analysis.

In another study, Guldager et al. (1992) investigated the effect of chelation treatment with EDTA in patients with severe intermittent claudication. Guldager et al. (1992) cited that no controlled clinical trials had been published on the possible effects of chelation therapy in patients with arteriosclerosis.

Guldager et al. (1992) conducted a randomized, double-blind, and placebo-controlled clinical trial in a group of patients. Significant benefits of chelation therapy among patients with intermittent claudication were

identified. The subjects (N = 159) were patients from several departments of vascular surgery in Denmark. The sample included patients over 40 years of age who suffered from stable intermittent claudication for at least 12 months. Benefits were measured by obtaining subjective and objective data: (a) pain free walking distance, (b) maximal walking distance, (c) ankle/blood pressure index of each extremity, and (d) subjective evaluation of improvement.

The sample of randomized clients were assigned to either an experimental or a control group. Prior to treatment, a physical exam was performed which included serum and urine tests. Verbal and written instructions were given regarding smoking cessation, physical training, dietary advice, and weight loss. Experimental and control solutions were prepared by the pharmacy. A total of 20 infusions over 5 to 9 weeks were completed in the outpatient department.

The effect of chelation therapy with EDTA was evaluated after the 20<sup>th</sup> infusion and at 3 and 6 months. Changes in parameters from pre-treatment to post-treatment in each patient were evaluated by analysis of variance. Sex, treatment, and smoking status were taken into



consideration. The interaction between treatment and sex, treatment and smoking, and age was simplified by eliminating non-significant ( $p > .05$ ) model terms. Subjective impression of the treatment was evaluated using the Wilcoxon test. Guldager et al. found no significant changes between the two groups with regard to medications, weight, diet, tobacco consumption, or exercise during the study. No significant increases in walking distance were noted in the group receiving EDTA or the placebo group. Ankle/brachial indexes were not significantly changed in either group. Subjective evaluation in both groups revealed 50% of the patients reported their intermittent claudication unchanged and the other 50% reported improvement. Serum alkaline phosphate lab for the EDTA group changed significantly ( $p = .001$ ). General, nonspecific side effects were identified but were not significant.

The researchers concluded that chelation therapy with EDTA did not demonstrate any effect in treatment of patients with intermittent claudication. Walking distance, pain-free walking distance, and ankle/brachial index parameters remained unchanged. Subjective evaluation showed no differences in the patient impression of the

therapeutic effect. Therefore, the researchers concluded that EDTA does not have a potential role in the clinical therapy and management of peripheral vascular disease. The researcher identified no recommendations for future studies.

The chosen study was reviewed due to the similarities to the current researcher's endeavors. This investigation also helped the current researcher to identify demographic and social habits of potential importance to the current study.

In a similar study, Olszewer and Carter (1988) investigated the effect of EDTA chelation therapy in chronic degenerative disease. In their review of the literature, the authors found that the benefits and effects of the administration of EDTA were found coincidentally in patients who were receiving the chelation for other reasons and found a lack of credible controlled clinical trials or double-blind studies of the effectiveness of EDTA.

Olszewer and Carter (1988) conducted a retrospective study of 2,870 patients with chronic degenerative diseases who were treated at a private clinic to identify significant benefits of chelation therapy. These benefits

were measured by obtaining objective: (a) clinical evaluation, (b) laboratory exams, (c) EKG, and (d) stress tests.

The sample of patients was from a private clinic in Sao Paul, Brazil. The protocol used was developed with 50 mg of EDTA per kilogram of body weight given in an IV infusion over a period of 3 to 3½ hours. Vitamins C, B complex, and magnesium were added to the solution for a total of 20 to 40 treatments. The treatments were given two to three times per week. The patients were also given orally combined multivitamin, mineral, and trace element preparations. They were encouraged to change their eating habits and to engage in a regular exercise program.

The patients were classified into the following vascular and degenerative disease categories: (a) cardiac, (b) peripheral vascular, (c) cerebrovascular and degenerative CNS disease, (d) scleroderma, and e) other geriatric vascular diseases. Patients were evaluated clinically according to claudication levels at rest and after stress, local temperature changes, trophic changes, and blood pressure and pulse. The noninvasive studies performed were Doppler with paper register and ultrasound. The results were classified into five groups according to

the following scale: (a) 4+, complete recovery; (b) 3+, good recovery; (c) 2+, regular recovery; (d) 1+, unchanged; and e) 0, worse than before treatment.

The results of this study revealed a total of 76.89% of the patients had a marked improvement, 16.5% were rated as having a good improvement, 3.79% were rated as having moderate improvement, and 2.5% were unchanged. Only 0.1% of the patients became worse. The results of this retrospective analysis suggest that chelation therapy with di-sodium magnesium EDTA was useful in the therapy of several thousand patients with chronic degenerative, especially cardiovascular diseases.

This study was significant to the current research because of the similarities. This retrospective study investigated the subjective effects of chelation therapy upon the clients.

In another study Casdorph (1981) investigated the effects of chelation therapy on the ejection fraction of the left ventricle in patients with arteriosclerotic heart disease. The purpose of this study was to not only observe a clinical response to chelation therapy, but to record objective measurements of cardiac function before and at the end of 20 infusions of the drug.

The sample size included 18 patients with documented arteriosclerotic disease. All patients had a complete physical and cardiac evaluation prior to the onset of therapy. Left ventricular fraction ejections were taken before and after the administration of chelation therapy. Each patient served as his or her own control by being studied before and at the end of the chelation infusions. The infusions were given once per week and were administered over a period of 3 hours in an office setting. During the chelation therapy, vitamin and mineral supplements were administered orally.

These data showed a statistically significant increase in the mean ejection fraction after the use of the chelation drug ( $p < .0005$ ). All patients improved clinically and in all but two there was a complete subsidence of angina during the course of chelation therapy. Of the two patients who did not have complete relief of chest pain, one patient had a marked amelioration of cardiac symptoms and the second patient had a 50% decrease in angina and a 12% increase in ejection fraction.

The author concluded that the intravenous administration of EDTA had been shown to bring clinical as

well as objective improvement in patients with documented arteriosclerotic heart disease. A statistically significant improvement was shown in the left ventricular ejection fraction in this group of patients who received chelation therapy.

This study is significant because of the similarities of investigating the effects of chelation therapy upon clients with arteriosclerotic changes. The current study investigated the effect of chelation therapy on clients with arteriosclerosis.

## Chapter III

### The Method

The purpose of this study was to determine the effect upon the perceptual quality of life and perception of pain in clients receiving chelation infusions. This chapter describes the research methods used to investigate the variables studied. The design, population, sample, and setting as well as instrumentation and methods of data collection are described in this chapter.

#### Design of the Study

A descriptive design was utilized to determine the effects of chelation therapy upon the perceptual quality of life and pain perception of clients receiving chelation therapy. A descriptive design is utilized to observe, describe, and document the aspects of a situation as it naturally occurs with no manipulation of variables (Polit & Hungler, 1995). Therefore, a descriptive design was deemed appropriate for this study as there was no manipulation of variables.

The dependent variables were the perception of the quality of life and the perception of pain in clients receiving chelation infusions. The independent variable within this study was the infusion of chelation drugs. The extraneous variables included the truthfulness of the subjects in completing the questionnaires, the subjects' age, race, past medical histories, and the use of other alternative interventions.

#### Research Questions

The following research questions were answered as a result of this study:

1. What is the effect of chelation therapy upon the perceptual quality of life in clients receiving infusions?
2. What is the effect of chelation therapy upon the perception of pain in clients receiving infusions?

#### Limitations

The following limitations were identified for this study:

1. The small sample size of this study made the results ungeneralizable.
2. The use of only one clinic in a southeastern state made the results ungeneralizable.



3. The wide range of past medical histories and the use of various medications may have influenced or impacted the clients' perceptions.

#### Setting, Population, and Sample

The setting for this study was a city in northeast Mississippi with a population of approximately 33,000 in the city and 64,000 in the surrounding county. The setting was one private clinic utilized for chelation therapy.

The population studied were clients receiving chelation infusions. The sample of convenience consisted of 24 participants between the ages of 20 and 70 years who were currently receiving infusions and were willing to participate in the study.

#### Methods of Data Collection

This section describes the method of data collected. A description of instrumentation procedures and method of data collected are included.

Instrumentation. The Medical Outcomes Study (MOS), a 12-item questionnaire, was used in this study (see Appendix A). The items included on the severity and effects of pain scales all correlated 0.5 or greater with their scale scores. Lateral consistency overall was 0.93;

for the effects score it was 0.91 and the severity score was 0.86. Correlation of the four pain measures with 15 criterion scores ranged from 0.43 to 0.57 (Sherbourne, 1992). These ranges supported the accuracy and consistency of measurement of pain. The MOS pain effects score was calculated by averaging across all six items, giving a score from 1 to 5 for each item; this was transformed to a 0 to 100 scale for the total score.

The European Organization for Treatment and Research of Cancer Quality of Life Questionnaire (EORTC QLQ-C30) used in this study was a 30-item questionnaire (see Appendix B). The EORTC QLQ-C30 used a linear transformation to standardize the raw score so that the scores range from 0 to 100; a high score represents a higher (better) level of functioning, or a higher (worse) level of symptoms (EORTC QLC Scoring Manual C30, 1995). Validity and reliability had been established by a panel of experts, but no statistics were found regarding reliability and validity. Demographic data were elicited through an 11-item questionnaire (see Appendix C). These included age, gender, race, routine medications, previous surgeries/illnesses, hospitalizations, number of treatments, time period that treatments were received,

diagnoses, social habits, and other alternative interventions that were used by the respondent. Also included was one open-ended question to assess any other information regarding benefits of chelation therapy or information that the respondent would like to share.

### Procedures

Following approval by the Committee on Use of Human Subjects in Experimentation at Mississippi University for Women (see Appendix D), the proposed site was contacted by letter (see Appendix E) for permission to distribute questionnaires to obtain information on the benefits of chelation therapy and demographic information about clients receiving chelation infusions. Subjects were informed both verbally by the staff nurse and with written instructions on the process of answering the questions. A clipboard and writing tool were provided by the researcher. The staff registered nurse was trained in the administration of the questionnaires by the researcher. The staff registered nurse was trained in the administration of the questionnaires by the researcher. The researcher reviewed all parts of the research and the directions related to the questionnaires with the clinic

staff registered nurse. The staff registered nurse working at the clinic administered the questionnaires which included a description of the purpose of the study and the participants' written consent (see Appendix F).

#### Method of Data Analysis

Data were analyzed using the Pearson product-moment correlation coefficient and descriptive statistics. The variables were measured on the ratio scale. Descriptive statistics were used to analyze the demographic characteristics of the respondents.

## Chapter IV

### The Findings

The purpose of this study was to determine the effects of chelation therapy upon the perceptual quality of life and perception of pain. A descriptive survey design was used for the study because it allowed the researcher to survey the effects of chelation therapy upon the perceptual quality of life and perception of pain. This chapter presents a description of the sample and the results of data analysis related to the research questions. Additional findings revealed during this study are also presented.

#### Description of the Sample

The sample consisted of 24 clients who received chelation therapy at a clinic in North Mississippi during a 2-week period. The Demographic Questionnaire was utilized to characterize the participants. Sixteen (66.7%) of the sample were Caucasian, 4 (16.7%) were African American, and 4 (16.7%) were Hispanic. Fifteen (62.5%) of the

participants were male, and 9 (37.5%) were female. At the time of the study, 3 (12.5%) of the participants had received a total of one to five chelation treatments, 14 (58.3%) had received 10 to 20 chelation treatments, and 7 (29.2%) had received over 30 chelation treatments. A large number ( $n = 15$ , 62.5%) of the group were over 60 years of age. The next largest age group consisted of individuals ages 51 to 60 ( $n = 6$ ) which represented 25% of the sample. Forty-one to 50 years old ( $n = 2$ ) represented 8.3% of the sample. A smaller number ( $n = 1$ , 4.2%) included individuals between the ages of 31 and 40 years.

Thirteen (54.3%) of the sample received chelation therapy over 6 months, 5 (20.8%) received chelation therapy from 6 to 12 months, 3 (12.5%) of the sample received chelation therapy from 1 to 2 years, 2 (8.3%) of the sample received treatments from 3 to 5 years, and 1 (4.2%) received chelation treatments from 5 to 10 years.

Analysis of medications consumed routinely, previous surgical procedures, and hospitalizations were also identified. A summary of the current diagnoses, social habits, and the use of alternative interventions is presented in Table 1. A section was included for client

comments. These additional findings will be discussed in Chapter V.

Table 1

Summary of Current Diagnoses, Social Habits, and Use of Alternative Interventions Expressed in Frequencies and Percentages

Client profile	f <sup>a</sup>	%
Current diagnosis		
Coronary artery disease	13	54.2
Arteriosclerosis	6	25.0
Cerebral vascular disease	8	33.3
Other diagnoses	5	20.8
Social habits		
Smoker	7	29.2
Exercise	14	58.3
Diet restrictions	6	25.0
Alcohol intake	4	8.3
Recreational drugs	0	0.0
Other alternative interventions		
Herbs/vitamins	15	59.0
Chiropractor	6	18.6
Magnets	3	9.8

<sup>a</sup>No. of participants reporting.

The Medical Outcomes Study (MOS) was utilized to determine the perception of pain. The domains included

bodily pain, pain and discomfort, duration of pain, pain associated with activities of daily living, and average and worst pain in the past 4 weeks.

The European Organization for Treatment and Research of Cancer Quality of Life Questionnaire (EORTC QLQ-C30), a 30-item questionnaire, was utilized to determine the effects of chelation therapy on the quality of life. Functional scales included physical functioning, role functioning, emotional functioning, cognitive functioning, and social functioning. Symptom scales included fatigue, nausea and vomiting, pain dyspnea, insomnia, appetite loss, constipation, diarrhea, and financial difficulties. Global health status was also included.

### Results of Data Analysis

The purpose of this study was to determine the effect of chelation therapy upon the perceptual quality of life and the perception of pain in clients receiving infusions. Data were elicited utilizing a demographic questionnaire, the MOS, and the EORTC QLC-C30 in order to answer the following research questions:

1. What is the effect of chelation therapy on the perceptual quality of life in clients receiving infusions?



2. What is the effect of chelation therapy on the perception of pain in clients receiving infusions?

The first research question for the study was "what is the effect of chelation therapy upon the perceptual quality of life in clients receiving infusions?" Data were analyzed using Pearson correlation statistics in a one-tailed test with a p value of  $< .05$  (critical  $r = 0.344$ ). With regard to quality of life, four significant items were identified by the EORTC QLQ-C30. These included an increase in cognitive functioning ( $p = .30$ ), decrease in fatigue symptoms ( $p = .021$ ), decrease in insomnia ( $p = .003$ ), and a decrease in financial difficulty ( $p = .026$ ) (see Table 2).

Table 2

Correlations of Chelation Treatments with EORTC QLQ-C30

Scales	r	p
SPF	.127	.277
SRF	.079	.357
SEF	.246	.124

(table continues)

Table 2 (Continued)

Scales	r	p
SCF	.388	.030*
SSF	.319	.065
GQL	.194	.182
SFA	.418*	.021
SNV	.123	.284
SPA	.050	.408
SDY	.070	.373
SSL	.540*	.003
SAP	.022	.459
SCO	.128	.275
SDI	.101	.319
SFI	.402*	.026

Note. N = 24. SPF = Personal functioning. SRF = Role functioning, SEF = Emotional functioning, SCF = Cognitive functioning, SSF = Social functioning, GQL = Global health status, SFA = Fatigue, SNV = Nausea and vomiting, SPA = Pain, SDY = Dyspnea, SSL = Insomnia, SAP = Appetite loss, SCO = Constipation, SDI = Diarrhea, SFI = Financial difficulties.

\*p < .05.

The second research question for the study was "what is the effect of chelation therapy upon the perception of pain in clients receiving infusions?" Descriptive statistics were used to analyze these data. A large percentage (64.44%) rated their bodily pain on a scale of none to mild, while 28.9% rated their pain from moderate to severe. Only 6.66% rated their pain as extreme. Interference in activities of daily living due to pain indicated that 54.87% had no interference. Duration of pain experienced was less than 60 minutes by 87.5% of the clients and 12.5% experienced pain from several hours to more than 2 days. A "little bit" of pain was experienced by 29.78% and "quite a bit" to moderate pain was experienced by 7.69% (see Table 3).

Table 3

Ratings of Pain of Clients Receiving Chelation Therapy  
Expressed in Frequencies and Percentages

Pain	%
Intensity of pain	
None to mild	64.40
Moderate to severe	28.90
Extreme	6.66

(table continues)

Table 3 (continued)

Pain	%
Duration of pain	
60 minutes or less	87.50
Several hours to > 2 days	12.50
Interference with activities of daily living	
None	54.87
Little bit	29.78
Quite a bit to moderate	7.69
Extremely	7.66

Note. N = 24.

#### Additional Findings

Several additional findings were identified during the study. Two of the clients reported that although they had no known disease, they were utilizing chelation therapy as a preventative measure against disease. A large percentage (75%) of the research participants engaged in additional forms of alternative interventions including vitamins, herbs, magnets, and chiropractors. Although for the most part, chelation therapy is not covered by insurances, one insurance company was found to cover the costs of chelation therapy.

## Chapter V

### The Outcomes

Alternative health care practices are a source of controversy among health care providers. Consumers of health care recently have been bombarded via the media about the pros and cons of a variety of alternative therapies. Because of the confusion among health care providers and the inevitable questions from consumers, it is essential for the health care provider to be familiar with new practices and interventions that may ultimately benefit these clients. There is very little research on the benefits of chelation therapy to clients receiving infusions. Thus, a descriptive survey design was used to determine the perceived quality of life and perceived pain control of clients receiving chelation therapy. Pender's nursing theory (Marriner-Tomey & Alligood, 1998) provided the theoretical basis for this study. The following research questions guided this study:

1. What is the effect of chelation therapy upon the perceptual quality of life of clients receiving infusions?

2. What is the effect of chelation therapy upon the pain perception of clients receiving infusions?

Three instruments were used to collect data. A Demographic Questionnaire was used to determine the demographic variables of age, race, preexisting illnesses, current medications, number of treatments, and the use of other alternative interventions. The Medical Outcomes Study (MOS) was used to assess the perception of pain. The European Organization for Treatment and Research of Cancer Quality of Life Questionnaire (EORTC QLQ-C30) was used to determine the perceptual quality of life. This chapter provides a discussion of the findings and presents conclusions, implications for nursing, and recommendations for future investigations.

#### Summary of Findings

The sample consisted of 24 clients receiving chelation therapy. The largest number ( $n = 15$ , 62.5%) were over 60 years old. The age group of 51 to 60 included 6 (25%) of the group. Forty-one to 50-year-old included 2 (8.3%) of the sample. A smaller number ( $n = 1$ , 4.2%) included individuals between the ages of 31 and 40 years. Males represented 15 (62.5%) of the sample, and females

represented 9 (37.5%) of the sample. Caucasians represented 16 (66.7%) of the sample, and 8 (16.7%) were African American. Sixteen (54.3%) of the sample received treatments from 0 to 6 months, 5 (20.8%) received treatments from 6 to 12 months, 3 (12.5%) of the sample received treatments from 6 to 12 months, 2 (8.3%) received treatments from 3 to 5 years, and one received treatments from 5 to 10 years.

Fifty-four percent ( $n = 13$ ) of the sample had coronary artery disease. Twenty-five percent ( $n = 6$ ) of the sample had arteriosclerosis. Thirty-three percent ( $n = 8$ ) of the sample had cerebral vascular disease. The other 20% had diagnoses, such as hypertension, diabetes, and angina. Fifty-eight percent ( $n = 14$ ) of the sample exercised regularly. Twenty-five percent ( $n = 6$ ) of the sample were on dietary restrictions. Also, 29.2% ( $n = 7$ ) of the sample were smokers. Other alternative interventions were used by 89% of the sample which included herbal treatments, vitamin therapy, and chiropractics.

The first research question for this study was to determine the effects of chelation therapy upon the perpetual quality of life. The effect of chelation therapy

on the perceptual quality of life revealed that only 4 of the 15 domains were statistically significant values: (a) cognitive functioning ( $p = .030$ ), (b) decrease in fatigue ( $p = .021$ ), (c) decrease in insomnia ( $p = .003$ ), and (d) decrease in financial difficulty ( $p = .026$ ).

The second research question was to determine the effects of chelation therapy upon the perception of pain. A large percentage (64.44%) of clients rated their bodily pain on a scale of none to mild, while 28.9% rated their body pain on a scale of moderate to very severe and 6.6% rated their pain as severe. Duration of pain experienced was less than 60 minutes by 87.5% of the clients. The majority of clients (54.8%) stated that pain did not interfere with their activities of daily living.

## Discussion

Statistical findings were significant in four areas of the perception of the quality of life in clients receiving chelation infusions. There was an increase in cognitive functioning and a decrease in fatigue, insomnia, and financial difficulties. The three domains may be interrelated because a client who experiences decreased insomnia, decreased fatigue, and are less tired and



sleeping well will most likely have better cognitive skills. The fourth area that was statistically significant, decreased financial difficulty, is probably related to the fact that most of the clients receiving chelation therapy at this clinic were financially independent and knew that all services were on a cash basis with little chance for reimbursement from health insurance.

These findings differ from Van Rij et al. (1994) who found no significant changes in behaviors and attitudes related to lifestyles. These differences support this researcher's belief that more studies related to the efficacy of alternative health methods are needed. No other studies were identified in the literature related to quality of life for individuals receiving chelation.

In Guldager et al. (1992) the subjects experienced no significant change in their pain. While this study did not compare pre- and post-chelation pain levels, only a very small percentage (6.6%) reported significant pain, and over half of the clients said that their pain did not interfere with activities of daily living. One can only surmise that the treatment helped clients to decrease pain while increasing activities of daily living.

In a separate section of the tool, clients had an opportunity to add any comments related to chelation therapy. Ten clients responded with the overwhelming sentiment being that their lives had significantly improved since beginning chelation therapy. Although this study provided a subjective measure of clients' perceptions whether the effect of chelation was real or placebo, the overall perceived health of the clients did improve.

The Health Promotion Model identifies motivational mechanisms for the client which include perceived benefits of behavior and selecting healthy lifestyle behaviors. The findings of this study showed that clients included the use of other alternative interventions and dietary changes which promoted healthy lifestyles. While it may be that these were perceived, rather than actual benefits, they often improved a client's overall perception of their health. The findings of this study support the Health Promotion Model's basic tenets that a client who is motivated by the perception of the importance of health-promoting behaviors, perceived control of his or her own health, the perception of efficacy of healthy behaviors,

and finally the perceived benefits of the behaviors will, therefore, engage in activities to support these beliefs.

In this study the clients were very motivated and felt very strongly that these behaviors were efficacious as well as beneficial. The clients also perceived that going to the clinic on their own was a way of controlling their own health. Approximately 80% engaged in additional alternative methods as an adjunctive therapy to chelation. The findings of this study support the establishment of the problem and the theoretical framework. The Health Promotion Model identifies motivational mechanisms for the client which include perceived benefits of behavior and selecting healthy lifestyles. The findings of the study showed the use of other alternative interventions and dietary changes promoted healthy lifestyles for the clients who took part in the study.

### Limitations

The researcher identified several limitations of this research study. The sample was small; therefore, it would be difficult to generalize to a larger population. The sample only included clients currently receiving chelation therapy at one clinical site; therefore, the perception of benefits received may have been biased. Another limitation

was that the researcher had no way of knowing the clients' prior health status. Although most stated that they felt better, the researcher had no data to compare the client's health status pre- and post-study.

### Conclusions

This research found that four distinct areas related to quality of life improved and that pain among this population of clients, nearly all of whom had a chronic illness, was negligible. This researcher inferred that clients' overall perception of their health had significantly improved since the initiation of chelation therapy. The clients seemed convinced that this was a positive health behavior, thus supporting the current trend of increased usage of a myriad of alternative therapies.

The difference between the positive results of this study and the few other existing studies, which found no improvement or changes in the clients' quality of life or pain, points out the need for further studies in this area. Alternative methods are often expensive and not covered by health insurance companies. Therefore, it is imperative to either validate their significance or quantify their uselessness as valid medical therapies.

### Implications for Nursing

This study had several implications for nursing that were derived from the findings. Consumers and clients are often knowledgeable regarding alternative practices and other interventions. These same consumers will often seek out health care providers to answer questions related to these regimens. Education for health care providers regarding the use and implications of alternative therapies is, therefore, essential for nursing. Because chelation along with other alternative methods are very vogue now, the nurse practitioner needs to be prepared to answer queries related to these methods.

Currently, many alternative practices have not been recognized by medical planners, insurance companies, or health care policy makers. Recently, many of those same planners, companies, and policymakers have begun to take a second look at these methods and even suggested reimbursement for certain alternative therapies. Research that includes the study of alternative practices should be conducted so that these methods can be validated if they are useful in the treatment of disease. Nurse practitioners can be an integral part of investigational studies related to alternative practices. By expanding

this study, a multitude of alternative methods and their effects on a clients health can be studied.

#### Recommendations for Further Study

Based upon the findings of this study, the following recommendations are made:

##### Research.

1. Replication of this study in another geographical area with a larger sample size.

2. Conduction of a similar study with a longitudinal research design that could follow the client over a longer period of time.

3. Replication of this study which allows the researcher to compare the client's health status prior to and during chelation therapy.

##### Nursing.

1. Education of health care providers with information related to both traditional and alternative health care methods.

2. Conduction of more research which incorporates the Health Promotion Model in examining health behaviors.

3. Encouragement by health care providers to scientifically explore alternative health care practices.

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APPENDIX A  
MEDICAL OUTCOMES STUDY

## Medical Outcomes Study (MOS)

1. How much bodily pain have you generally had during the past 4 weeks? (Circle one)
  - ☐ None
  - ☐ Very mild
  - ☐ Mild
  - ☐ Moderate
  - ☐ Severe
  - ☐ Very severe
2. During the past 4 weeks, how often have you had pain or discomfort? (Circle one)
  - ☐ Once or twice
  - ☐ A few times
  - ☐ Fairly often
  - ☐ Very often
  - ☐ Every day or almost every day
3. When you had pain during the past 4 weeks, how long did it usually last?
  - ☐ A few minutes
  - ☐ Several minutes to an hour
  - ☐ Several h ours
  - ☐ A day or two
  - ☐ More than 2 days
4. During the past 4 weeks, how much did pain interfere with the following things: (Circle one number on each line)

	Not at all	A little bit	Quite a bit	Moderately	Extremely
a. Your mood	1	2	3	4	5
b. Your ability to walk or move about	1	2	3	4	5
c. Your sleep	1	2	3	4	5
d. Your normal work (including both work outside the home and housework)	1	2	3	4	5
e. Your recreational activities	1	2	3	4	5
f. Your enjoyment of life	1	2	3	4	5

5. During the past 4 weeks, how many days did pain interfere with the things you usually do?

(Your answer may range from 0 to 28 days)

Write in number of days: \_\_\_\_\_

6. Please circle the one number that best describes your pain on the average over the past 4 weeks.

No  
pain

Pain as  
bad as  
you can  
imagine

0 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20

7. Please circle the one number that best describes your pain at its worst over the past 4 weeks.

No  
pain

Pain as  
bad as  
you can  
imagine

0 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20

APPENDIX B  
EORTC QLQ-C30

ENGLISH

**EORTC QLQ-C30** (version 3)

We are interested in some things about you and your health. Please answer all of the questions yourself by circling the number that best applies to you. There are no "right" or "wrong" answers. The information that you provide will remain strictly confidential.

Please fill in your initials:

--	--	--	--	--

Your birthdate (Day, Month, Year):

--	--	--	--	--	--	--	--

Today's date (Day, Month, Year):

31							
----	--	--	--	--	--	--	--

	Not at All	A Little	Quite a Bit	Very Much
1. Do you have any trouble doing strenuous activities, like carrying a heavy shopping bag or a suitcase?	1	2	3	4
2. Do you have any trouble taking a <u>long</u> walk?	1	2	3	4
3. Do you have any trouble taking a <u>short</u> walk outside of the house?	1	2	3	4
4. Do you need to stay in bed or a chair during the day?	1	2	3	4
5. Do you need help with eating, dressing, washing yourself or using the toilet?	1	2	3	4
<b>During the past week:</b>				
6. Were you limited in doing either your work or other daily activities?	1	2	3	4
7. Were you limited in pursuing your hobbies or other leisure time activities?	1	2	3	4
8. Were you short of breath?	1	2	3	4
9. Have you had pain?	1	2	3	4
10. Did you need to rest?	1	2	3	4
11. Have you had trouble sleeping?	1	2	3	4
12. Have you felt weak?	1	2	3	4
13. Have you lacked appetite?	1	2	3	4
14. Have you felt nauseated?	1	2	3	4
15. Have you vomited?	1	2	3	4

## ENGLISH

**During the past week:**

	Not at All	A Little	Quite a Bit	Very Much
16. Have you been constipated?	1	2	3	4
17. Have you had diarrhea?	1	2	3	4
18. Were you tired?	1	2	3	4
19. Did pain interfere with your daily activities?	1	2	3	4
20. Have you had difficulty in concentrating on things, like reading a newspaper or watching television?	1	2	3	4
21. Did you feel tense?	1	2	3	4
22. Did you worry?	1	2	3	4
23. Did you feel irritable?	1	2	3	4
24. Did you feel depressed?	1	2	3	4
25. Have you had difficulty remembering things?	1	2	3	4
26. Has your physical condition or medical treatment interfered with your <u>family</u> life?	1	2	3	4
27. Has your physical condition or medical treatment interfered with your <u>social</u> activities?	1	2	3	4
28. Has your physical condition or medical treatment caused you financial difficulties?	1	2	3	4

**For the following questions please circle the number between 1 and 7 that best applies to you**

29. How would you rate your overall health during the past week?

1            2            3            4            5            6            7

Very poor

Excellent

30. How would you rate your overall quality of life during the past week?

1            2            3            4            5            6            7

Very poor

Excellent



APPENDIX C  
DEMOGRAPHIC QUESTIONNAIRE

## Demographic Questionnaire

Height:\_\_\_\_\_ Weight:\_\_\_\_\_ Recent weight changes:\_\_\_\_\_

Please check the appropriate response(s) to the following questions:

## 1. Present age (years)

\_\_\_\_\_ 20 to 30  
\_\_\_\_\_ 31 to 40  
\_\_\_\_\_ 41 to 50  
\_\_\_\_\_ 51 to 60  
\_\_\_\_\_ Over 60

## 2. Gender

\_\_\_\_\_ Male \_\_\_\_\_ Female

## 3. Race

\_\_\_\_\_ Black \_\_\_\_\_ Hispanic  
\_\_\_\_\_ White \_\_\_\_\_ Other (please specify):\_\_\_\_\_

## 4. Number of treatments

\_\_\_\_\_ 1 to 5  
\_\_\_\_\_ 10 to 20  
\_\_\_\_\_ Over 20

## 5. Time period of treatments

_____ 0 to 6 months	_____ 5 to 10 years
_____ 6 to 12 months	_____ 10 to 15 years
_____ 1 to 2 years	_____ > 15 years
_____ 3 to 5 years	

## 6. Medications: (Please list and include supplemental vitamins)

_____	_____
_____	_____
_____	_____

## 7. Previous surgeries/illnesses

_____	/
_____	/
_____	/

8. Hospitalizations for illnesses  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_
9. Diagnosis (check all that apply)  
\_\_\_\_ Corney artery disease  
\_\_\_\_ Arteriosclerosis disease  
\_\_\_\_ Cerebral vascular disease  
\_\_\_\_ Other (please specify): \_\_\_\_\_
10. Social habits (Check all that apply)  
\_\_\_\_ Smoker  
\_\_\_\_ Exercise regularly  
\_\_\_\_ Diet restrictions (Please explain): \_\_\_\_\_  
\_\_\_\_ Alcohol intake  
\_\_\_\_ Recreational drugs  
\_\_\_\_ Other (Please specify): \_\_\_\_\_
11. Other alternative interventions currently being used or  
have used in the past  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_
12. Comments:  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

APPENDIX D

APPROVAL OF COMMITTEE ON USE OF HUMAN  
SUBJECTS IN EXPERIMENTATION OF  
MISSISSIPPI UNIVERSITY FOR WOMEN



MISSISSIPPI  
UNIVERSITY  
FOR WOMEN

*Admitting Men Since 1982*

Office of the Vice President for Academic Affairs  
Eudora Welty Hall  
W-Box 1603  
Columbus, MS 39701  
(601) 329-7142

March 22, 1999

Ms. Francine Glenn  
c/o Graduate Program in Nursing  
Campus

Dear Ms. Glenn:

I am pleased to inform you that the members of the Committee on Human Subjects in Experimentation have approved your proposed research as submitted provided you add a statement to the consent form that participation is voluntary and election not to participate will in no way affect care, that the participant may withdraw at any time without penalty, and that any assistant employed shall be trained and educated in the requirements of confidentiality.

I wish you much success in your research.

Sincerely,

Susan Kupisch, Ph.D.  
Vice President  
for Academic Affairs

SK:wr

cc: Mr. Jim Davidson  
Dr. Mary Pat Curtis  
Dr. Linda Sullivan

APPENDIX E  
AGENCY CONSENT FORM

### Consent for Participation

I have been fully informed of this study investigating the effects of chelation therapy upon the perceptual quality of life and perception of pain. I agree to allow Francine S. Glenn to collect data from consenting clients at my clinic. In no way will the clients' willingness to participate affect the services they receive at this facility.

I am also aware that the information gathered at this facility will remain confidential and will be used in a masters thesis by Francine S. Glenn at Mississippi University for Women.

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Date

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Signature of Physician

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Date

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Signature of Physician

APPENDIX F  
LETTER TO PARTICIPANT AND CONSENT



May 29, 1999

Dear Participant,

I am a registered nurse presently pursuing a Master of Science in Nursing degree at Mississippi University for Women in Columbus, Mississippi. I am conducting a study that will look at the benefits of chelation therapy. Your opinions and experiences are very important and are needed to provide an accurate portrayal of your perception of the level of satisfaction of life and pain perception since receiving chelation infusions. Please assist me in this study by completing the attached questionnaire.

Strict confidentiality will be maintained regarding access to information and only group scores will be recorded. Only my research committee will have access to data obtained. There will be no means of identification of participants with questionnaires that are filled out. I sincerely hope that you will complete and return the questionnaire to the clinic staff. If at any time during the questionnaire process you would like to withdraw from the study, please inform the clinic staff and appropriate actions will be taken. Please sign below indicating permission to participate in the study.

Thank you for your cooperation and assistance in this study.

Sincerely,

Francine Glenn, RN, BSN

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I, \_\_\_\_\_, agree to participate in the study investigating the subjective benefits of chelation therapy.